Quality Management Plan–
Revision No. 1
"Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources"

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REVISION HISTORY:

Revision Number	Date	Revision
0	October 2012	New document
1	January 2012	1. Replaced Robert Puls with David Jewett as Overall Technical Research Lead and Technical Research Lead for Case Studies 2. Replaced Steve Vandegrift with Stephen Watkins as the Program QA Manager 3. Updated Figures 3 and 4 to reflect the changes in 1 and 2. 4. Section 1.3: Added program quality assurance as an oversight function of the Office of Science Policy. 5. Section 1.4: Replaced Steve Vandegrift with Stephen Watkins as the Program QA Manager

EPA does not consider this internal planning document an official Agency dissemination of information under the Agency's Information Quality Guidelines, because it is not being used to formulate or support a regulation or guidance; or to represent a final Agency decision or position. This planning document describes the overall quality assurance approach that will be used during the research study. Mention of trade names or commercial products in this planning document does not constitute endorsement or recommendation for use.

Table of Contents -

List of Figures

List of Tables

Abbreviations and Acronyms -

AA	Assistant Administrator
ADQ	Audit of Data Quality
ANSI	American National Standards Institute
ASQ	American Society for Quality
CBI	Confidential Business Information
CFR	Code of Federal Regulations
CIO	Chief Information Officer
COC	Chain of Custody
COR	Contracting Officer's Representative
DOE	United States Department of Energy
DQA	Director of QA
DQO	Data Quality Objectives
ECMS	Enterprise Content Management System
EPA	United States Environmental Protection Agency
FTP	File Transfer Protocol
GWERD	Ground Water and Ecosystems Restoration Division
HAZWOPER	Hazardous Waste Operations and Emergency Response
HF	Hydraulic Fracturing
IA (IAG)	Interagency Agreement
IQG	Information Quality Guidelines
ISO	International Organization for Standardization
L/C/O	Laboratory/Center/Office
NCCT	National Center for Computational Toxicology
NCEA	National Center for Environmental Assessment
NERL	National Exposure Research Laboratory
NETL	National Energy Technology Laboratory
NRMRL	National Risk Management Research Laboratory
NRP	National Research Program
NWPP	National Watershed Protection Program

OEI	Office of Environmental Information
ORD	Office of Research and Development
ORISE	Oak Ridge Institute for Science and Education
OSP	Office of Science Policy
OW	Office of Water
PE	Performance Evaluation
PQAM	Program Quality Assurance Manager
QA	Quality Assurance
QAM	Quality Assurance Manager
QARF	Quality Assurance Review Form
QAPP	Quality Assurance Project Plan
QC	Quality Control
QMP	Quality Management Plan
QSA	Quality System Audit
RLO	Records Liaison Officer
TSA	Technical Systems Audit
TSCA	Toxic Substances Control Act
USGS	United States Geological Survey
SAB	Science Advisory Board
SIO	Senior Information Officer
SOP	Standard Operating Procedure
SSC	Student Services Contract
SSWR	Safe and Sustainable Water Resources

1. Management and Organization

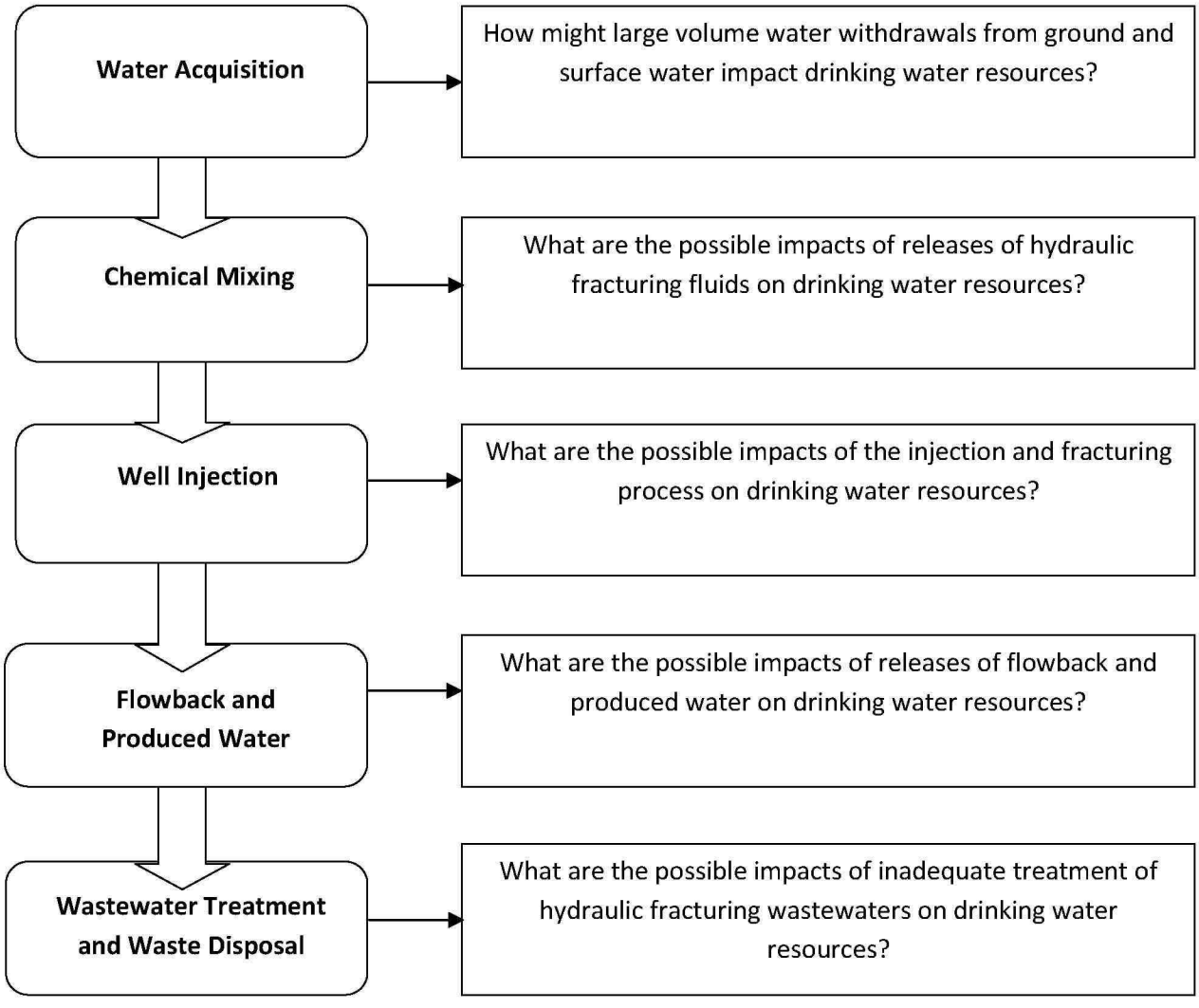
1.1. Introduction

As natural gas production has increased, so have concerns about the potential environmental and human health impacts of hydraulic fracturing (HF) in the United States. Hydraulic fracturing, which involves the pressurized injection of water, chemical additives, and proppants into a geologic formation, induces fractures in the formation that stimulate the flow of natural gas or oil, thus increasing the volume of gas or oil that can be recovered from coalbeds, shales, and tight sands—the so-called "unconventional" reservoirs. Many concerns about HF center on potential risks to drinking water resources, although other issues have been raised. In response to public concern, Congress directed the United States Environmental Protection Agency (EPA) to conduct research to examine the relationship between HF and drinking water resources.

The overall purpose of this study is to understand the relationship between HF and drinking water resources. More specifically, the study is designed to examine the conditions that may be associated with the potential contamination of drinking water resources and to identify the factors that may lead to human exposure and risks. The scope of the proposed research includes the full lifecycle of water in HF, from water acquisition through the mixing of chemicals and actual fracturing to the post-fracturing stage, including the management of flowback and produced water and its ultimate treatment and/or disposal. Figure 1 illustrates the HF water lifecycle and the key research questions EPA will address through this study. EPA consulted with experts in the field through peer review and technical workshops and engaged stakeholders in a dialogue about the study through facilitated public meetings. The draft *Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources* (1) was developed to describe the specific research activities that will be performed. Retrospective and prospective case studies will be used along with generalized scenario evaluations.

This draft Study Plan was reviewed by the Science Advisory Board (SAB). The comments of the SAB were incorporated into the final Study Plan. EPA has established a website for HF Research activities and associated documents (http://water.epa.gov/type/groundwater/uic/class2/hydraulicfracturing/index.cfm).

Figure 1. HF Research Program Fundamental Research Questions



The significant national interest in this HF Research Program requires a rigorous quality assurance (QA) approach to include:

- Research projects must comply with Agency requirements and guidance for quality assurance project plans (QAPPs), including the use of systematic planning.
- Technical systems audits, audits of data quality, and data usability (quality) assessments will be conducted as described in QAPPs.
- Performance evaluations of analytical systems will be conducted (if available).
- Products will undergo QA review.

- Reports must have a readily identifiable QA section.
- Research records will be managed according to EPA's record schedule 501 for *Applied and Directed Scientific Research* (2).

1.2. Quality Policy

In order to ensure that results are scientifically defensible, the HF Research Program will comply with the Agency-wide Quality Policy CIO 2106 (3) (4) and other quality requirements as listed below:

- EPA Order CI0 2105.0 (5, 6) or the most recent change to the Order;
- EPA's Information Quality Guidelines (IQG) (7);
- EPA's Laboratory Competency Policy (8);
- ORD Policies and Procedures Manual, Chapter 13, Quality Assurance (9).

The development, review, approval, and implementation of this quality management plan (QMP) is part of the mandatory Agency-wide Quality System that requires EPA and all organizations collecting environmental data for EPA to develop and operate management processes and structures for assuring that data or information collected are of the needed and expected quality for their desired use. This QMP complies with the Agency policy and includes coordination of research across multiple EPA Laboratories, Centers, and Offices as well as extramural research support. This QMP provides the necessary elements to plan, implement, document, and assess the effectiveness of QA and quality control under the HF Research Program.

1.3. Technical Approach Summary

This HF Research Program involves multiple EPA Laboratories, Centers, and Offices within the Office of Research and Development (ORD). The EPA Office of Science Policy (OSP) is the lead organization to provide oversight functions such as overall budget management, study coordination, and program quality assurance, as well as evaluates and synthesizes collected HF information and data. ORD Laboratories and Centers participating in the HF Research Program include:

- National Risk Management Research Laboratory (NRMRL) –
  - Case Studies, Lab Studies, Wastewater Treatment and Disposal, Surface Water Modeling
- National Exposure Research Laboratory (NERL) –
  - Scenario Evaluation and Modeling, Analytical Chemistry
- National Center for Computational Toxicology (NCCT) –
  - Toxicology Assessment
- National Center for Environmental Assessment (NCEA) -
  - Toxicology Assessment

EPA Regions will be involved in the case study projects to provide logistical support and analytical laboratory support, and will also perform well file reviews. Other Federal entities, such as the United

States Geological Survey (USGS) and the Department of Energy-National Energy Technology Laboratory (DOE-NETL) will provide research support for case studies through Interagency Agreements (IAs). Contractors will provide support for case studies in the field and laboratory, for modeling activities, with existing data activities (compiling, evaluation, analysis, etc.), and with QA support.

Extramural support is anticipated from:

- the USGS (IA with NRMRL/GWERD);
- ERG, Westat, and Cadmus (contract support for the Office of Science Policy);
- Post-doctoral personnel (ORISE with NCEA and NCCT);
- Office of Water (OW) National Watershed Protection Program (NWPP) (contract with NERL);
- Ecology & Environmental (contract support for GWERD);
- Shaw (contract support for GWERD);
- Lawrence Berkeley National Laboratory (IA with NERL);
- Students (Student Services Contracts (SSCs) for NCEA, NCCT, NRMRL, and NERL); and
- Others as determined to be needed.

Technical Research Leads have been assigned to the following HF research areas: Case Studies, Analytical Chemistry, Toxicology Assessment, Scenario Evaluation and Modeling, Wastewater Treatment/Disposal, and Data Analysis. These areas are encompassed by the five key stages of the HF water lifecycle: Water Acquisition, Chemical Mixing, Well Injection, Flowback and Produced Water, and Wastewater Treatment/Disposal as shown in Figure 1. Appendix A of the HF Study Plan provides a summary of the research projects that will be conducted under this HF Research Program.

1.4. Quality Approach Summary

This document provides QA guidance to all personnel associated with the EPA's efforts to conduct the congressionally mandated HF Research Program (1). The intent of this QMP is to document QA procedures and practices that are required under the HF Research Program and to specify the roles with respect to QA.

This QMP will be implemented in coordination with existing EPA organizational QMPs. All technical and QA personnel will implement their organization's QMP. Additionally, requirements in this HF Research Program QMP must be met to ensure consistency in the QA approach for all participating organizations. The HF Research Program is supported by a Program QA Manager (PQAM), Stephen Watkins (OSP), who will assist the technical and QA staff in implementing this QMP. Table 1 presents a summary of responsibilities for both L/C/O QA Managers (QAMs) and the PQAM.

Table 1. Responsibilities of Laboratory/Center/Office (L/C/O) QA Managers and Program QA Manager (PQAM)

	Planning	Implementation	Assessment	Products
L/C/O QAM Responsibilities	QA review/approval of QA Review Forms (QARFs), and QAPPs	QA review/approval of Protocols, standard operating procedures (SOPs), and Methods	Conducting or overseeing Technical Systems Audits, Audits of Data Quality, Performance Evaluations; preparation of audit reports; reporting status of corrective actions to L/C/O management and PQAM	QA review/approval of L/C/O products
PQAM Responsibilities	Review QARFs for consistency with QMP requirements; provide guidance for QAPP preparation; provide concurrence that QAPPs meet HF Research Program requirements*; ensure that QAPPs are approved via communication with QAM/Director of QA (DQA) of associated L/C/O; and tracks approved QAPPs	Provide consultation if needed.	Track status of corrective actions for Findings.	QA review and approval of consolidated HF Research Program products with assistance from L/C/O QA staff

*This is not a "QA review"

1.5. Expected Products and Associated Reviews

The two primary products from this HF Research Program are two reports (2012, 2014). In addition to these reports, there may be other EPA reports, journal articles; symposium/conference papers; extended abstracts; computer products (software, models, databases, scientific data); and EPA web pages . Prior approval from the ORD AA's office must be obtained before dissemination of any products which present HF Research Program results.

Each technical report needs to include a description of the QA activities performed during the research. The data reported in products will be adequately documented and characterized, including a thorough description of limitations or qualifiers wherever appropriate

Technical products produced in the HF Research Program are required to undergo QA review prior to release. The SOP (http://intranet.epa.gov/nrmintra/lsas/eqmp/pdf/SOPLSASQA010.pdf) (10) can be consulted for example guidance regarding product QA reviews.

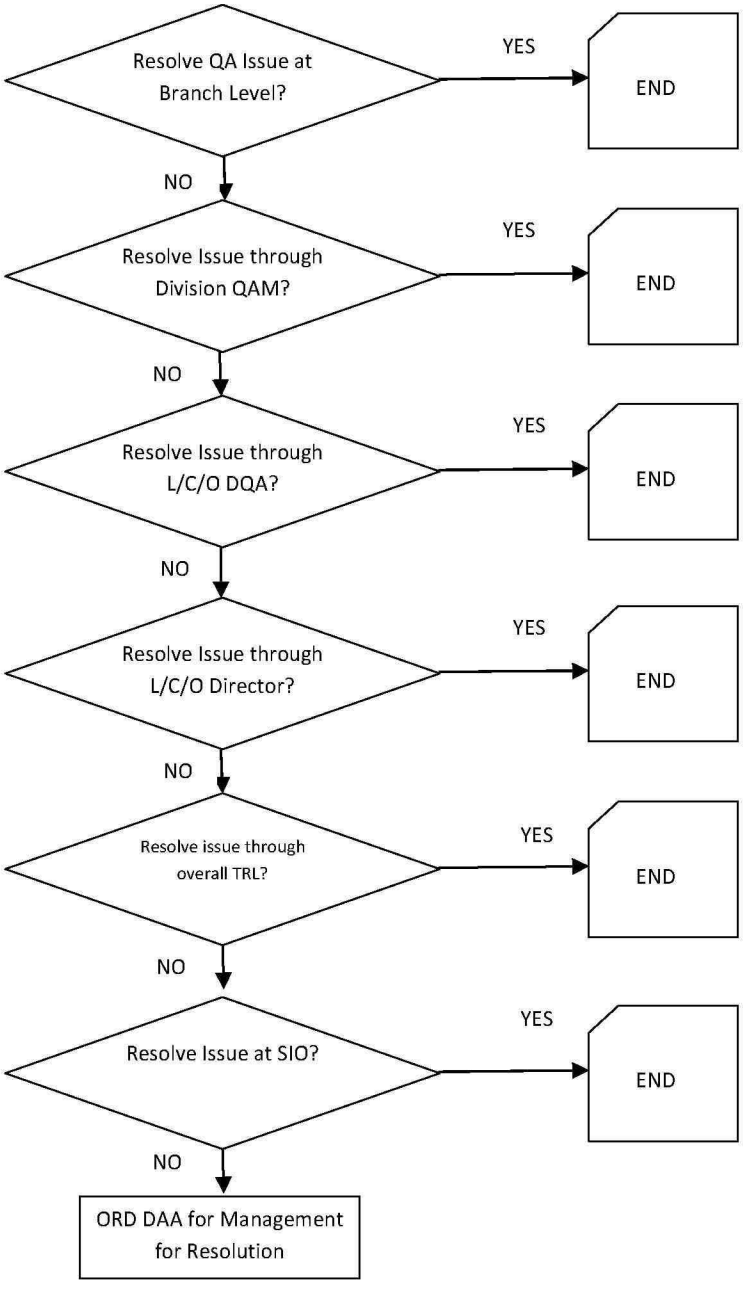
Peer reviews are documented critical reviews of scientific or technical work products by qualified individuals or organizations. Peer reviewers are independent of the researchers but have relevant substantive expertise. Peer reviews must be documented and include an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them. See *U.S. Environmental Protection Agency Peer Review Handbook*, 3rd Edition, 2006 (11). External panel peer reviews will be performed on the 2012 and 2014 reports. For other products, at a minimum, EPA-internal peer review will be performed. Additional peer reviews may be required per individual L/C/O procedures.

All HF research products must be submitted for clearance. QA approval must be documented in the clearance package per L/C/O procedures. Peer reviews and associated responses are also included in the clearance packages. The specific requirements for product clearance are described in each L/C/O-specific QMP. Additionally, clearance at the AA level will be needed.

1.6. Dispute Resolution

Oversight responsibilities for QA/quality control (QC) may sometimes result in disagreements between the QA staff and project management. Such disputes may occur in situations involving technical issues (e.g., audits, surveillances, data quality assessments) and management issues (e.g., QAPP reviews). All QA problems should be resolved at the lowest possible management level. The respective organization's QMP will be followed for dispute resolution. If the issue cannot be resolved within the L/C/O per their QMP requirements, the appropriate Technical Research Lead and his/her management shall be consulted for resolution. If the issue still cannot be resolved, it will be elevated to the Overall Technical Research Lead. The PQAM shall be included in negotiations of these dispute resolutions if they rise above the L/C/O. If the Technical Research Lead is the same person as the Overall Technical Research Lead, then the step involving the Overall Technical Research Lead shall be skipped and the dispute resolution procedures described in the draft ORD QMP (12) will be invoked and include the ORD Senior Information Officer and the ORD Deputy AA for Management (Figure 2). The ORD DQA shall be consulted in the negotiations. The ORD Deputy AA for Management is the ultimate decision maker for resolving disputes.

Figure 2. QA Dispute Resolution Flowchart



1.7. Roles and Responsibilities

All HF Research Program personnel are responsible for the quality of research and the quality of output derived from activities under their control or influence, and are accountable to appropriate line managers, and ultimately to the respective L/C/O Directors. Figures 3 and 4 present the HF Research Program organization and identify those personnel with HF Research Program responsibilities.

Each Key Investigator with project lead responsibilities, i.e., Principal Investigator (PI) or Contracting Officer's Representative (COR), identified in Figure 3 is responsible for ensuring data collected for their project is of acceptable quality for their intended use and ensuring that no data gathering begins until the QAPP is approved. It is the responsibility of his/her Branch Chiefs, Division Directors, and QAMs to provide project management/QA approval for associated QAPPs and products. The PQAM will work closely with the L/C/O QAMs, DQAs, and the technical staff to ensure that the QA/QC documents and procedures are adequate to meet the needs and objectives of the HF Research Program. It is the responsibility of the L/C/O Division QAMs to audit the projects within their L/C/O.

Specific roles and responsibilities for personnel involved in these HF research activities are presented in the following sections.

National Program Director

- Reviews and approves this HF Research Program QMP
- Responsible for implementation of the HF Research Program QMP

Study Coordinator

- Coordinates the overall HF Research Program, operating principles, implementing activities, and annual budgets
- Reviews, approves, and assists in the revision of this HF Research Program QMP
- Distributes final QMP to HF Research Program personnel (delegated to PQAM)
- Ensures HF Research Program participants are trained in the requirements of the QMP (may be delegated)

Director Office of Science Policy

- Provides communication avenues to support the activities of the Study Coordinator
- Reviews and approves this HF Research Program QMP
- Ensures the HF Research Program QMP is implemented

Figure 3. Hydraulic Fracturing Study Research Team

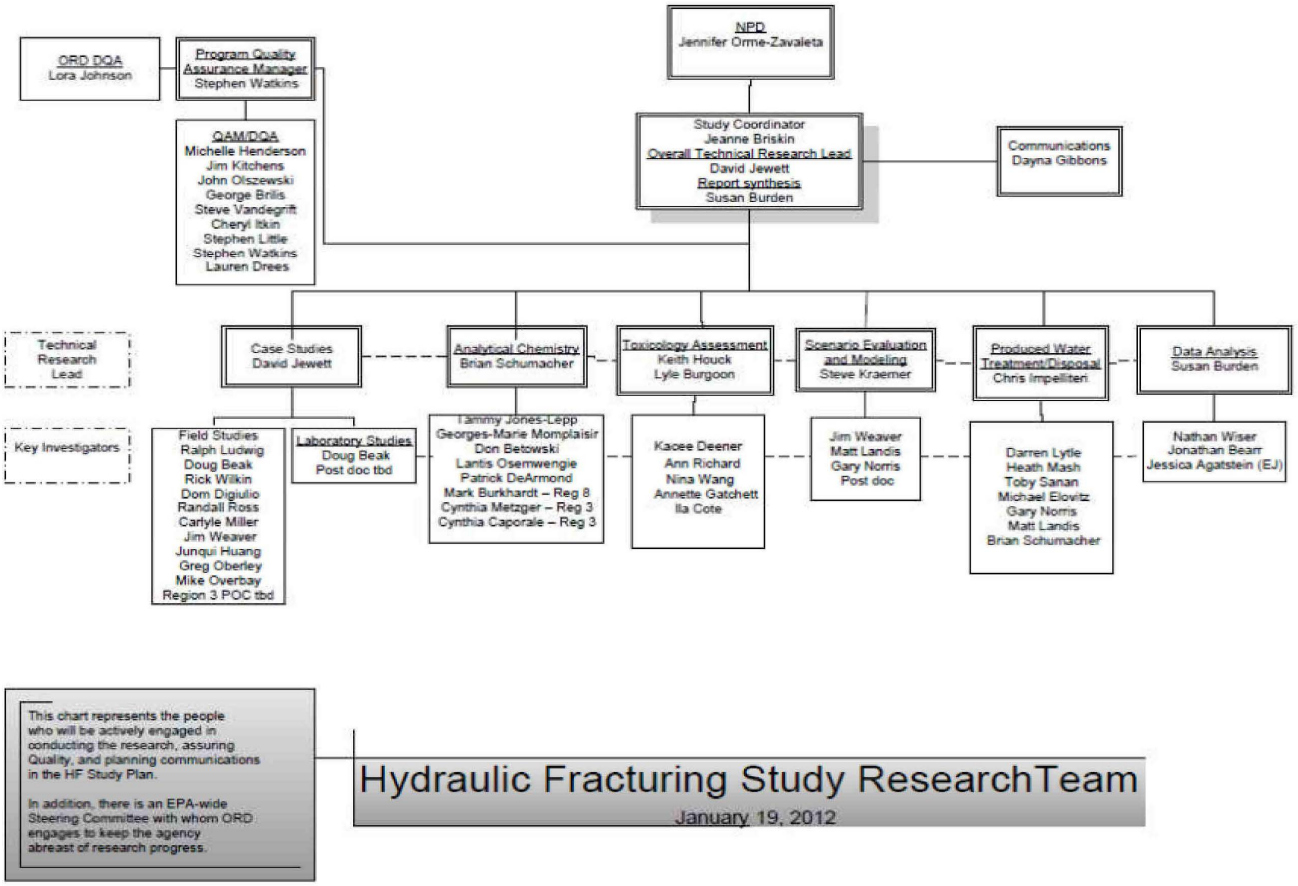
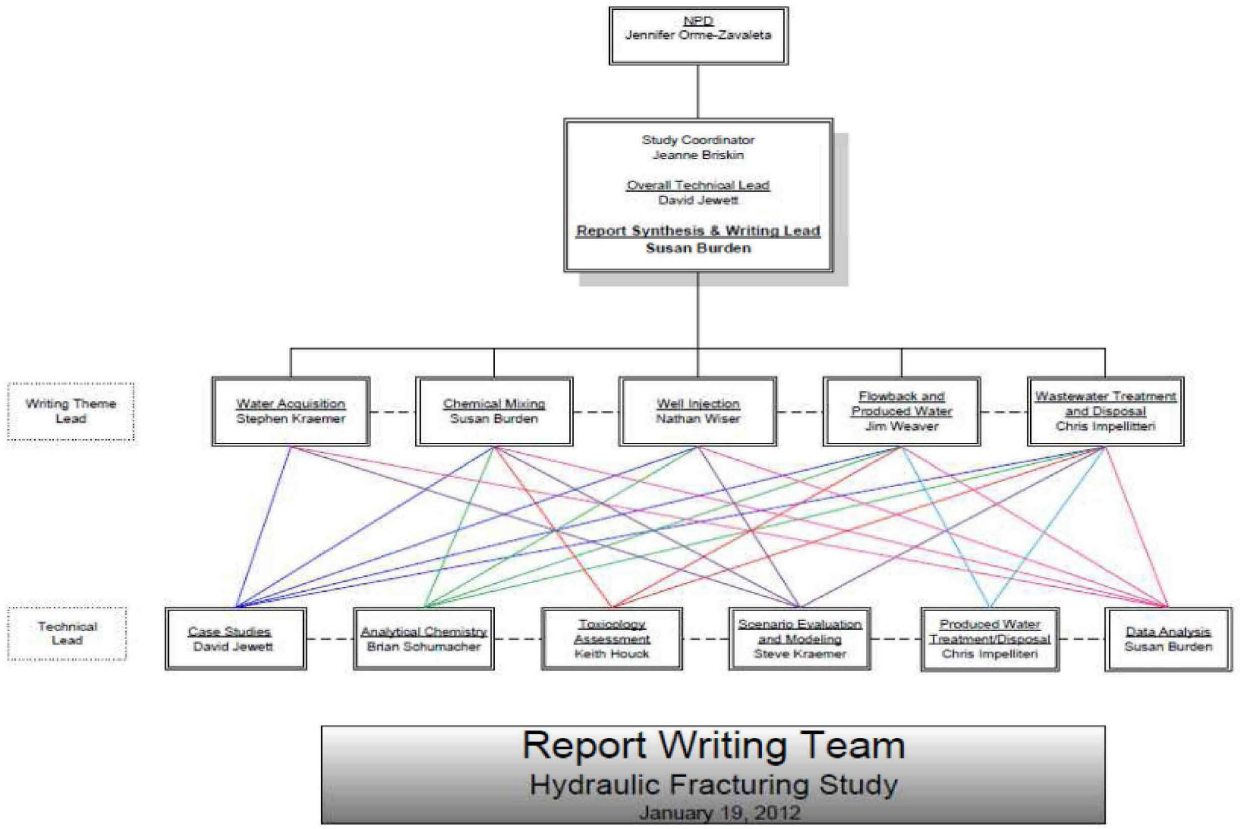


Figure 4. Hydraulic Fracturing Study Report Writing Team



Overall Technical Research Lead

- Reviews, approves, and assists in the revision of this HF Research Program QMP
- Ensures the HF Research Program QMP is implemented
- Oversees and coordinates the technical aspects of HF Research Program research areas
- Provides dispute resolution for QA problems that are elevated above the Technical Research leads

Theme Leads

- Synthesizes the information and data collected from each research area that is relevant to their theme and writes relevant sections of reports
- Ensures readily identifiable QA section is prepared and included in all HF reports

Technical Research Leads

- Ensures the HF Research Program QMP is implemented
- Oversees and coordinates all research activity within their research area
- Approves QAPPs within their research area
- Provides dispute resolution for QA problems that are elevated above a L/C/O
- Reviews products within their research areas

L/C/O Directors

- Implements annual HF Research Program budgets and resource allocations
- Allocates personnel and other resources to accomplish this HF Research Program's goals
- Performs the responsibilities outlined in their respective L/C/O QMP
- Ensures this HF Research Program QMP and associated QA System is implemented

L/C/O Branch Chiefs, Division Directors

- Performs the responsibilities outlined in their respective L/C/O QMP
- Ensures the HF Research Program QMP is implemented
- Allocates appropriate personnel and other necessary resources to support this HF Research Program
- Ensures that products from this HF Research Program are reviewed by the QAM and approved prior to publication
- Approves QAPPs for Key Investigators that lead the preparation of QAPPs that directly report to them
- Review products for Key Investigators that directly report to them

Key Investigators (this includes Project Leads, support personnel for Project Leads, and CORs)

- Leads or assists in the preparation of QAPPs and ensures these plans are approved prior to starting work
- Ensures QA Review Forms are completed for all extramural activities
- Ensures the approved QAPP is implemented
- Ensures all personnel working on the research are adequately qualified and trained for their assignments
- Performs the responsibilities outlined in their respective L/C/O QMP
- Schedules audits and assessments with their associated QAM
- Manages the official record copies of all documents generated during the research life cycle

ORD Director of QA

- Assists in the development and refinement of this QMP
- Facilitates QA problem resolution
- Performs a Quality Systems Audit of the HF Research Program within one year of QMP approval
- Provides QA support to the HF Study Coordinator as needed (e.g., QA review and approval, audits)

Program QAM (PQAM)

- Serves as liaison for QA between the HF Research Program and the L/C/O DQAs and Division QAMs
- Informs QA staff on HF Research Program QA developments and accomplishments and unresolved HF Research Program QA issues
- Develops, implements, maintains, and provides training in the HF Research Program's Quality Management Plan
- Tracks QA activities across the HF Research Program
- Reports QA activities and problems to the associated L/C/O Director of QA or QA Manager and to appropriate HF Research Program personnel
- With the assistance of the responsible L/C/O QA staff, ensures that all HF Research Program QA/QC documents (QA Project Plans, Operating Procedures/Standard Operating Procedures, QA Review Forms for extramural research, reports, etc.) are prepared and approved according to L/C/O policies and HF Research Program QA requirements
- With the assistance of the responsible L/C/O QA staff, reviews and approves the QA portions of published HF Research Program reports
- With the assistance of the responsible L/C/O QA staff, ensures that all HF Research Program consolidated products are reviewed and approved by L/C/O QA staff
- Organizes teleconferences for ORD QA staff involved with the HF Research Program

L/C/O Directors of QA (DQA) responsibilities

- Performs the responsibilities outlined in their respective L/C/O QMP
- Reviews and approves HF Research Program-related QA/QC documents generated in their respective L/C/O if not done at the Division level
- Facilitates problem resolution and tracking corrective action

L/C/O QAM's responsibilities (including the DQA for NCEA)

- Performs the responsibilities outlined in their respective L/C/O QMP
- Reviews and approves HF Research Program-related QA/QC documents generated in their respective L/C/O and Division
- Upon receipt of QAPPs for QA review, submits QAPPs to the PQAM for concurrence that they meet HF Research Program requirements
- Performs audits (technical systems audits [TSAs], audits of data quality [ADQs], performance evaluation [PEs]) of HF Research Program-related projects performed in their respective L/C/O and Division
- Report to the PQAM the status of corrective actions identified in audits quarterly
- Communicates HF Research Program-related QA issues to the PQAM
- Facilitates problem resolution and tracking corrective action
- Provides QA input for Division activities into the QA portion of published HF Research Program reports
- Ensures audits are conducted without conflict of interest by the auditor(s)/assessor(s)
- Reviews and approves all technical products (e.g., reports, journal articles, models, data summaries, etc.) produced within their organization from this HF Research Program
- Participates in activities organized by the HF PQAM and other HF Research Program leaders, e.g., teleconferences
- Provides HF Research Program QMP training to HF Program personnel in their respective L/C/O or Division

Program Records Management Consultant (Brian Devir, ORD Records Liaison - OSIM)

- Provide related input to QMP
- Assist HF Research Program personnel in understanding and implementing HF Research Program records management requirements

Program Data Management Consultant (Dave Lyons – OSIM)

- Provide related input to QMP
- Assist HF Research Program personnel in understanding and implementing data management requirements

ORD QA staff (i.e., DQAs, QAMs) whose organizations are involved in the HF Research Program will support the PQAM's efforts to coordinate QA/QC practices. This will be accomplished by ensuring QA/QC requirements are included in QA documentation and by conducting assessments of the

appropriate type and frequency to evaluate the implementation of planned QA/QC practices. The DQAs/QAMs are responsible for ensuring the required HF Research Program QA activities are conducted according to this QMP and their organization's QMP. QAPPs prepared by individuals for specific research areas will be approved by those individuals' respective Division QAMs after consulting with the PQAM that the QAPP meets the HF Research Program requirements.

2. Quality System Components and Description

This Quality System and QMP apply to all research activities conducted under this HF Research Program. EPA management will review and approve this QMP and subsequent revisions as QA policy for this HF Research Program.

2.1. Graded Approach

EPA applies a graded approach to all QA requirements such that process of basing the level of application of QA requirements to an item or work is graded according to the intended use of the results and the degree of confidence needed in the quality of the results. In ORD, the application of this graded approach is based upon a four category system, with Category 1 requiring the most stringent QA requirements:

Category I: Research that directly or immediately supports specific Agency rule-making, enforcement, regulatory, or policy decisions (12). This category may also include research of significant national interest, such as tasks that might be monitored by the Administrator.

All projects under this HF Research Program have been designated as ORD QA Category 1 efforts because of the potential impacts of the results generated. QA categories are described further in the Office of Research and Development *draft Quality Management Plan*, dated April 2011 (12). Category I projects must comply with Agency requirements and guidance for QAPPs, including systematic planning. QAPPs will be required to adhere to the requirements in *EPA Requirements for Quality Assurance Project Plans* (13). For Category I projects, audits are needed, reports must have a readily identifiable QA section, and products must undergo QA review and approval. EPA Records Schedule 501 applies to this QA category (2).

Key Investigators with project lead responsibilities will prepare project-specific QAPPs (see Appendix A of the HF Research Program Study Plan for research areas and projects) as described in Section 7. Project specific QA documents, including QAPPs, will be reviewed and approved by the L/C/O QAMs with concurrence by the PQAM.

Organizational-specific products from this HF Research Program will also be reviewed and approved by the L/C/O QAMs. Consolidated products that encompass information from across ORD will be approved by the PQAM, with assistance from the L/C/O QAMs.

Quality, management, and technical assessments will be included throughout the HF Research Program as described in Section 9.

2.2. Planning Components

2.2.1 Study Plan

The planning for the HF Research Program began with the Congressional mandate and significant stakeholder input that followed. Stakeholder input has been critical in planning the HF Research Program. Federal, state, tribal partners as well as industry, non-governmental organizations, and the public were engaged via webinars, sector-specific meetings, and public information meetings. Written and electronically submitted comments were also solicited and incorporated into the planning. This input was reviewed by the SAB and incorporated into the *Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources* (1) – the technical basis for this QMP and HF Research Program.

2.2.2 Systematic Research Planning and QAPPs

The research performed for this HF Research Program will use the goals and objectives in the Study Plan referenced above, and then develop project-specific objectives. Systematic planning must be applied in the planning process. In some cases, this may include utilization of the data quality objective process. This data quality objectives (DQO) process is described in *Guidance on Systematic Planning using the Data Quality Objectives Process*, (14). Project-specific quality documentation will also include QAPPs, Standard Operating Procedures (SOPs), and similar planning and procedural documents. Section 7.0 of this QMP provides more specific information.

2.2.3 QA Review Forms for Extramural Activities

QA requirements need to be identified by the COR (with concurrence by the L/C/O QAM) for each extramural action and incorporated into the extramural documentation. Specific information is provided in Section 4.0.

2.3. Implementation Components

2.3.1 Routine Communications

The following teleconferences/meetings/reports will be used throughout the HF Research Program to communicate project requirements, status, and activities:

Bi-weekly:

- The Study Coordinator will provide bi-weekly updates of HF Research Program activities to the ORD Deputy Director for Science.

Monthly:

- The PQAM will lead a monthly (actual frequency may vary at discretion of PQAM) status communication (teleconference or email) of the quality and information management with the DQAs/QAMs.

- The Study coordinator will host monthly teleconferences to discuss the progress towards milestones, complications, and any other current topic of interest or concern. QA will be a topic on these teleconferences when deemed necessary by the PQAM.
- Technical Research Leads and key investigators will provide monthly reports to the HF Research Program Communication Lead regarding stakeholder outreach activities (e.g., invitations to speak at meetings about HF Research Program activities).

Quarterly:

- The Overall Technical Research Lead will host steering committee meetings to keep interagency organizations informed of the current progress and any other current topic of interest or concern.

As Needed:

- Extended videoconferences hosted by the Study Coordinator

2.3.2 Training

Training requirements are described in Section 3.

2.4. Assessment Components

Assessments are an essential part of the HF quality system. Details of the assessments that are required are presented in Section 9. In all instances it is vital that the auditor(s)/assessor(s) ensure there is no real or perceived conflict of interest with the project/system/organization being audited/assessed. It is the responsibility of the QAM to ensure audits are conducted without conflict of interest.

Assessment components are introduced here:

- Quality system audits (QSAs)
- Technical systems audits (TSAs)
- Performance evaluations (PEs)
- Verification of Data
- Audits of data quality (ADQs)
- Data usability assessment
- Readiness reviews
- Surveillance

3. - Personnel Qualification and Training

The HF Research Program requires that all research and QA staff have appropriate qualifications and training to meet their assigned responsibilities. Line managers are responsible for identifying those key

work functions at each organizational level requiring special skills and for establishing procedures to ensure that personnel demonstrate proficiency in performing their assigned work methods. Individual L/C/O QA staff will determine the necessary QA training needs via discussions with employee assignments, and as a result of findings from audits or assessments.

HF Research Program QA training in the requirements of this QMP will be performed by the PQAM via the periodic QA teleconferences and monthly teleconferences lead by the Study Coordinator described in Section 2.3. Additionally, HF Research Program QMP training materials will be prepared by the PQAM and distributed to L/C/O QAMs. The L/C/O QAMs will be responsible for training L/C/O personnel as needed.

Any project- or task-specific specialized training or certification requirements will be identified and described in QAPPs. Hazardous Waste Operations and Emergency Response (HAZWOPER) certification is required for all case study field work, including for those conducting QA and safety audits. Anyone working with confidential business information (CBI) must undergo training and be certified to handle this information. Legal access to Toxic Substances Control Act (TSCA) CBI is dependent upon meeting the conditions found in Section 14 of TSCA. The qualifications differ between federal employees and contractor employees and may require administrative certification. Key investigators with project lead responsibilities are responsible for ensuring that personnel working on their projects receive this training if necessary.

Specific HF Research Program training will include training in communications procedures and email record-keeping (using ECMS). Training will be provided by the HF Research Program Communication lead and the ORD Records Liaison Officer, respectively. The timing and participants for these trainings will be determined by the Study Coordinator.

EPA and contracted laboratories and contractors performing the field sampling must demonstrate competency in accordance with *Agency Policy Directive FEM-2011-01* (15). Documentation of competency may include participation in applicable certification and/or accreditation programs where this is available for the fields of analysis. Guidance may be found at the EPA Forum on Environmental Measurements site http://www.epa.gov/fem/accredit.htm.

Contracting Officer Representatives (CORs) are responsible for ensuring contractors have the necessary qualification for their assigned work and required qualifications for extramural contracts and those personnel.

4. Procurement of Items and Services -

All operations performed under extramural agreements shall comply with the Agency-wide Quality System requirements as defined by the relevant regulations. Such agreements include: contracts, cooperative agreements, grants, and interagency agreements. ORD QA Review Forms (16) for extramural agreements (http://intranet.epa.gov/nrmintra/lsas/eqmp/pdf/qarford071508.pdf) will be prepared by individual CORs and approved by their respective Division QAMs after consulting with the PQAM. Instructions on using this form are available here http://intranet.epa.gov/nrmintra/lsas/eqmp/pdf/ORDQARFinstructions073008.pdf.

Federal procurement and financial assistance regulations provide specific requirements for QA/QC whenever environmental data collection or use is expected as part of a project or activity. The specific requirements apply to the following:

- Any organization or individual under direct contract to EPA to furnish services or items or perform work (i.e., a contractor) under the authority of 48 Code of Federal Regulations (CFR), Chapter 15, Part 46 [10];
- Institutions of higher education, hospitals, and other non-profit recipients of financial assistance (e.g., Grants and Cooperative Agreements) under the authority of 40 CFR Part 30 [11]; and
- State, local, and Tribal governments receiving financial assistance under the authority of 40 CFR Parts 31 and 35 [12].

Non-EPA quality systems that comply with the document *Quality Systems for Environmental Data and Technology Programs* (17) or the *Uniform Federal Policy for Implementing Environmental Quality Systems* (18) (http://www.epa.gov/fedfac/pdf/ufp_v2_final.pdf) are also in compliance with EPA policy.

Interagency agreements (IAs) that are funded by EPA should include EPA QA/QC requirements in the agreement. Because EPA cannot unilaterally impose such requirements, these requirements must be negotiated into each agreement and include references to the consensus standard ASQ/ANSI E-4 (17)or equivalent EPA requirements (QA/R-2, Reference 19, QA-R-5, Reference 13). QA review forms for extramural agreements will be approved by individual CORs and their respective Division QAMs after consulting with the PQAM.

The steps and required QA used in the procurement of items and services under this HF Research Program are largely handled in each L/C/O QMP. Extramural items or services sponsored by or obtained for the HF Research Program will be subject to basic QA requirements established by Federal, Agency, and L/C/Os policies and regulations. All extramural documents and records that will be transferred to the EPA during or at the completion of the project should be specified in the Statement of Work (SOW) or external agreement.

4.1. Contract Support

Considerable laboratory, field work, and other contract support are anticipated during the course of this research. In general, the originating COR has the responsibility for QA for the procurement activity, in consultation with the QAM. EPA policy requires a completed QA Review Form (16) (http://intranet.epa.gov/nrmintra/lsas/eqmp/pdf/qarford071508.pdf) with each extramural project funding package to document the QA requirements. The COR must then ensure that the requirements are included in the contract language. These contracted laboratories, field personnel, and other facilities have QA responsibilities that are specified in their respective SOW associated with their contract. A SOW shall be developed by the COR and provided to their QAM for QA review along with an ORD QA Review Form (QARF). Upon receipt, the QAM shall forward the QARF to the PQAM for review of HF Research Program consistency. The QAM shall review the SOW and QA Review Form to ensure the QA requirements meet these HF Research Program's requirements. If needed, the QAM shall provide review comments to the COR who will make the necessary revisions to comply with these requirements.

QA responsibilities and requirements for contractors include, but are not limited to:

- Accredited laboratories shall be used for critical target analytes; if accreditation is not feasible, then laboratory competency shall be demonstrated (documented quality system and in place, documented methods, instrumentation and experience, performance evaluations, independent audits)
- Contractor activities shall be audited by the EPA for those performing analysis of critical target analytes (see Section 9)
- Maintain communication with the EPA
- Develop or implement QAPPs as specified in the SOW
- Perform the required QA/QC procedures during technical or analytical activities
- Report technical or analytical results with associated QA/QC summary and datum specific information
- Perform corrective actions or other necessary steps when QA issues are identified and reporting this information to the associated EPA L/C/O.

The contracted laboratory, field personnel, or facility personnel should have a Quality Manager, Officer, or similar defined position that is responsible for ensuring these responsibilities are conducted. The QAM/officer of the contractor must be independent of the data being collected.

4.2. Interagency Agreements

The HF Research Program will implement Interagency Agreements (IAs or IAGs) to augment their capabilities in areas such as lab and field support as well as research activities. QA requirements will be negotiated between the EPA and the other Federal Agency and documented in the ORD QA Review Form as well as the Decision Memorandum, including who has the lead for QA. Upon receipt, the QAM shall forward the QARF to the PQAM for review of HF Research Program consistency. After receiving

concurrence from the PQAM, the QA Review Form and Decision Memorandum shall be reviewed and approved by the QAM. Typical requirements include several approaches: the federal agency develops and writes a QAPP to be reviewed and approved by the EPA, they implement an EPA-approved QAPP, or they implement well-documented protocols or methods that are reviewed and approved for use by EPA. The work conducted under an IA shall be audited by EPA (Section 9).

When dialogue results in a final determination of these requirements, the final requirements shall be documented in the project QAPP.

4.3. Supplies

The Key Investigator shall establish and appropriately document in the procurement specifications the necessary QA/QC requirements of the needed supplies. Verification that these supplies meet the requirement is the responsibility of the Key Investigator, or his/her designee.

4.4. Regional and ORD Laboratories

EPA Regional and ORD laboratories will provide analytical support for the HF Research Program. They shall be subject to same QA requirements as contracted laboratories. The Key Investigator in consultation with the QAM must clearly transmit requirements to the EPA laboratory and participate in discussions as needed to ensure requirements will be met. The requirements shall be documented in the project QAPP.

5. Documents and Records -

All research related documents and records are the property of the Federal government and are subject to the Federal records management policies.

All research projects conducted by or for the HF Research Program must be documented in accordance with ORD's Policy and Procedures Manual, Chapter 13, Section 13.2: *Paper Laboratory Records* (9). All federal records will be maintained and stored according to Agency guidelines. As a QA Category 1 effort, the majority of HF Research Program research records require permanent retention under EPA Records Schedule 501 *Applied and Directed Scientific Research* (2).

Extramural documents and records will be organized in a contract file or an assistance agreement file by the COR. Scientific records are to be transferred to the EPA Key Investigator at their request at the end of the project. The Key Investigator/COR for each project will ensure that the final project/contract/assistance agreement file is properly assembled for archiving. The scientific records generated as part of extramural actions will be retained in the project file to comply with the Records Schedule identified above.

5.1. Use of the O:\ Drive

This HF Research Program will utilize a central information management system as a repository and central location for storing, sharing, and archiving study documents, data, and other record materials. Oversight of the system, including server operations, maintenance, and back-ups is the responsibility of OSIM. Electronic records (other than email) shall be filed on the shared ORD drive, O:\. By selecting the O:\ drive, study participants across all ORD locations may easily collaborate by sharing access to individual files. Collaborators at other EPA locations (i.e. Regional offices) can also be granted access to the O:\ drive. Access to folders can be controlled using a hierarchical structure that begins with O:\ Priv. Access rights are one of the following:

- read,
- read, write, and delete.

The Study Coordinator or designee will maintain an Excel spreadsheet of all study participants that require access to the O:\Priv drive and their associated access rights. This spreadsheet will be shared with OSIM staff that is responsible for administering access rights on the O:\ drive. Study participants will be granted read and write access to all HF folders with the exception of files that are designated for documents and records for which the technical review process, including QA review, is completed. For these files, only the Study Coordinator (and designee) and Report Synthesis Lead Author will have read, write, and delete access; all other users will have read-only privileges.

The EPA ORD shared network group drives are not approved electronic record keeping systems as defined by the National Archives. Therefore, to organize electronic files for proper retention and disposition, they must to be grouped together by the retention schedule disposition item (e.g., 316-

258_501a2). In addition, electronic files need to be identified to the specific research project for which they were created. All HF Research Program participants are responsible for proper records retention. An example of the file structure that will be used to accomplish these objectives follows:

O:\Priv\NRP_SSWR_HF\316-258_501a2\20110228_QA_Assessment_ABC.doc

> ***O:*** *= the network common drive accessible to all of ORD*
>
> ***Priv****= Private, as opposed to Public. Access to this directory is controlled.*
>
> ***NRP****=National Research Program is a virtual organization identifier, since the research is not specific to a particular L/C/O*
>
> ***SSWR****=Safe and Sustainable Water Resources which is the national research program defined by ORD's Path Forward research portfolio that is accountable for the HF project*
>
> ***HF****=Hydraulic Fracturing (research project name)*
>
> ***316-258 501a2****=EPA file code (316-258 is the functional code for Applied Science; 501 is the EPA record schedule for Applied and Directed Scientific Research; and, a2 is the disposition item for Project Files)*
>
> ***20110228_QA_Assessment_ABC.doc****=the file name of a particular document. A standard YYYYMMDD format representing the date the file was created, followed by a subject name, followed by ABC, an optional component of the file name indicating the initials of the author. Underscores are used in place of spaces in the file name.*

The specific directory structure that will be used for the study and administered by OSIM can be found in Figure 5.

Technical Research Leads may use QAPPs to describe additional standard sub-folders within the O:\ drive file structure. Individual researchers may also create sub-folders within the O:\ drive file structure on an as needed basis. When researchers use "My Documents" for storing their electronic files, for example during initial data analyses, no standard file structure is required, however file names conforming to the conventions describe in 5.2 should be considered.

The O:\ drive file structure was constructed according to the following logic:

- Some literature will be used for analytical work (i.e. Literature_for_Analysis), other literature will be technical or general reference files which are maintained by individuals or program offices to enable the person or program office to perform its mission and which are kept only for reference and therefore placed in Literature_for_ Reference.
- Documents, data, and other record material will have a life cycle that includes initial collection, sharing and analysis. This information is typically held in electronic files. Prior to technical review and QA review, these types of electronic files will be stored according to the six

technical areas described in the HF organization chart (Figure 3) using Project_Files-QA_Incomplete.

- At the point in time when all technical reviews, including QA review, are complete, documents and data will be placed in Final_Project_File-QA_Complete . This folder will be access controlled in order to insure that all appropriate QA/QC checks have been completed and if any changes are required, that their impact can be assessed with respect to other aspects of the study. It is highly recommended that information in this folder be in pdf.
- The information that will be used to write the reports for Congress will be stored in Draft_Report_2012 using the same themes as used for the HF study plan reviewed by EPA's SAB. These six themes are depicted in the HF organization chart in Figure 3.
- The HF study has an overarching QA program described in this document. Key documents required for the QA program will be stored in Quality_Assurance.
- Records schedule 501 includes several retention schedules, ranging from permanent retention (i.e., 316-258_501a2) to retaining files for only 5 years after completion of the project (i.e., 316-258_501c). The majority of HF study files will be permanently retained; however any records for maintenance, calibration, or inspection of equipment will be placed in Equipment_Files, which has the shorter retention requirement.

A shortcut to the subfolders for the HF study has been created and may be copied to the desk top to avoid drilling down through the top level folders. It is located at O/PRIV/NRP_SSWR_HF and is labeled "HF Files on O Drive".

5.2. File Naming Conventions

General

The following conventions should be considered for naming files that are created as part of the HF study:

Avoid use of special characters in naming such as \ / : * ? < > | [ ] & $, .

These characters have different effects in various operating systems (Apple, Microsoft, Linux), their use could lead to loss of files or errors.

Avoid spaces in naming, use underscores instead.

Spaces are translated in a web environment as "%20" and in word processing spaces signal a possible break for a new line.

Consider that the file/folder will move from its original location.

Files are frequently moved (email, copied, etc) from the original location which may have given context. For example: genomic_lab\photos\microscope\00001.gif

While this method is efficient when the files stay in this directory structure, it could lose context if the files alone or just one level of folder were moved. An alternative would be: genomic_lab_photos_microscope_0001.gif

Consider using a date in your file and/or directory naming scheme.

As files are copied, their date of creation is overridden to the date of copy in some operating systems such as Microsoft XP.

If you do choose to use a date, follow the International Organization for Standardization (ISO) document 8601 (20). Numeric representation of dates and time which for dates is:

YYYYMMDD

Examples:

January 5, 2011	20110105
February 13, 1966	19660213
December 20, 1989	19891220

Manage versions.

To manage versions, consider adding a "v" to the file name followed by a two digit number, for example, "v02, v03, v04" to ensure capture of changes from the original. Once the action is completed and the final version released, change the "v" notation to "FINAL".

Examples:

virtualLiver_tox_study_v01.doc

virtualLiver_tox_study_v02.doc

virtualLiver_tox_study_FINAL.doc

Indicate who created the file.

Include the researchers name or initials in the file name.

Consistency.

Are versions important to your group or is it more important to include a date? What is most important is that as a whole there is consistency in our naming practices.

There will be exceptions.

One exception is batch processing by third party software. There are times when it is not possible to name files that are automatically generated. In these cases apply standardization to the directories in which they reside.

Literature Files

Journal Articles

AuthorLastName_etal_YYYY_JournalAbbreviation_ShortIdentifyingText.xyz
(The "etal" is only necessary if there is more than one author on the document)

Another option would be to use the following if two authors and the above etal version if more than two authors:

AuthorLastName1_AuthorLastName2_YYYY_JournalAbbreviation+ShortidentifyingText.xyz

Report

ReportPublisher_YYYY_ReportNumber_ShortIdentifyingText.xyz

Presentation

PresenterLastName_YYYYMMDD_MeetingAbbreviation_ShortIdentifyingText.xyz

5.3. Email Management

Record emails associated with the HF Research Program should be kept as part of the research project file or part of the project administrative correspondence, in the agency enterprise content management system, ECMS. Guidance on email as records (21) can be found at (http://www.epa.gov/records/faqs/email.htm). HF Research Program participants are responsible for ensuring that email records are added to ECMS at the end of the study or when the participant leaves the team for any reason.

So that HF Research Program emails can be compiled, accessed and stored from a central information system, an "organization" has been established in the ECMS database for the HF Research Program (e.g., ORD/NRP/SSWR/HF). Collaborators may register in ECMS for access to this organization file plan, as a secondary organization, by "Requesting a group membership change" (http://intranet.epa.gov/ecms/start/register.htm). Upon obtaining access, users shall file all project email in custom HF study folders already established in the file plan, which mimics what is displayed in Figure 5.

As ECMS "organization" folders, the contents of these folders are accessible to all members of the HF study, unless otherwise restricted by the email filer. Additional customized sub-folders may be requested by contacting the ORD Records Liaison Officer (RLO).

5.4. Alternatives to Sharing Data on the 'O' Drive

Guidance for alternatives to sharing data is provided in this section.

Small files (≤ 10 megabytes): Email is a quick and convenient option.

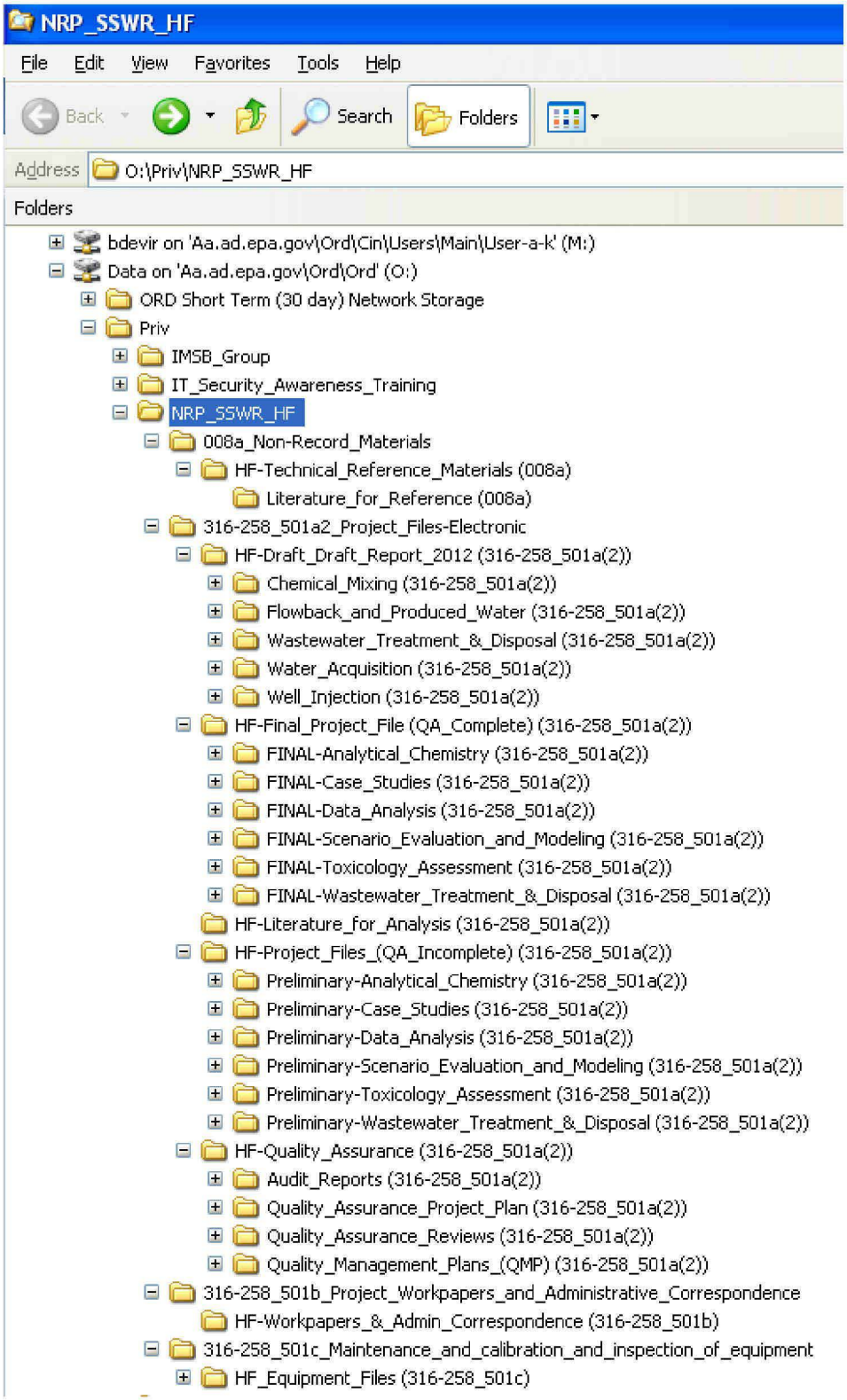
Medium files (10 megabytes to 100 gigabytes): Using the EPA's Science FTP Server is an option. FTP stands for File Transfer Protocol, a network protocol for copying files over a network such as the Internet. This service, run by the Office of Environmental Information (OEI), has been in operation since 2004 and is designed for both inbound and outbound file sharing. It is available to both EPA staff and external collaborators. Click on the link above to set up an account and create accounts for external collaborators. Generally collaborator accounts are good for 1 to 4 weeks, but you can request up to a year by emailing Ravi Nair at nair.ravi@epa.gov for an extension. Note: Files on the Science FTP are deleted after 28 days without prior notice. SFTP is not a place to store files like the O Drive which is backed up, it is a place to transfer files to other collaborators.

Large files (≥ 100 gigabytes): Use a removable hard drive and overnight delivery service.

5.5. Confidential Business Information (CBI)

In some instances work may entail use of documents or data that describe or involve CBI. Confidential business information is any information in any form received from any person, firm partnership, corporation, association, or local, state, or Federal agency which contains trade secrets or commercial or financial information, and which has been claimed as confidential by the person submitting it and which has not legally determined to be non-confidential by the EPA General Counsel. Toxic Substances Control Act CBI procedures will be used to maintain CBI collected under the HF Research Program (22). HF Research Program managers and staff must ensure that this information is protected from general release and is kept in a secure system as required by the above reference.

Figure 5. File structure for O drive and enterprise content management system



6. Computer Hardware and Software -

Procedures to ensure the accuracy and integrity of computer-resident data are of critical importance to the overall quality and credibility of the HF Research Program. The EPA OEI publishes guidance that will be generally followed throughout the EPA ORD L/C/Os participating. This guidance includes EPA Directive 2100B8, *Information Resources Management Policy* (23) and EPA CIO 2104.0, *Software Management and Piracy Policy* (24). These comprehensive guidance documents address many issues regarding the use of computer systems, including purchase of computers, purchase or development of software, design of databases, records management, security, and data standards. Network- and PC-based databases, and the networks themselves, will adhere to Agency information management standards developed by the Office of Information Resources Management and to other standards and guidelines as applicable for the development of software and specialized computer hardware. Specification for Computer Hardware and Software will be described in the individual L/C/O QMPs. It is the responsibility of each Key Investigator to interpret and adhere to the applicable standards (of their respective L/C/O) for each intramural or extramural project or study.

Projects that entail modeling, existing data, and require significant databases should specify computer hardware and software requirements in the associated QAPP. Should there be a need for project level software to be developed this will be described in individual planning documents and conducted according to the OEI guidance and requirements for: installing, using, maintaining, controlling and documenting hardware and software. Procedures for assessing and documenting the impact of changes to the system and for ensuring items meet necessary quality requirements prior to purchasing are included. These QAPPs must also follow EPA software, modeling, and database specific guidance, including EPA G-5M, Section 7.0 (25) if applicable.

If HF Research Program wide hardware or software is required (e.g., database), the Study Coordinator (or designee) is responsible for ensuring these systems adhere to the Agency information management standards.

7. Planning

EPA requires that all research conducted shall follow a systematic planning process. This HF Research Program has been designated as a QA Category 1 effort. All work conducted specifically for this HF Research Program must follow the minimum QAPP requirements as described in EPA/QA R-5 *EPA Requirements for QAPPs* (13). The guidance used to develop the project planning documents should be tailored to the project. Quality Management Tools for developing QA Project Plans are available at http://www.epa.gov/quality/qapps.html. EPA guidance is available for projects that expand beyond typical measurement projects. Research projects that entail Modeling should utilize the EPA Guidance QA/G-5M (25): *Guidance for QAPPs for Modeling*. When existing data are used, the QAPP should indicate how "good" the data or information must be to meet the objectives of the project. During the planning process, acceptance or performance criteria should be determined for the data and documented in the QAPP. Research projects that entail the use of Existing Data should utilize the EPA Guidance QA/G-5: *Guidance for QAPPs*, Chapter 3 (26).

Other agencies (e.g., DOE) may follow the *Uniform Federal Policy for Implementing Environmental Quality Systems* (18) (http://www.epa.gov/fedfac/pdf/ufp_v2_final.pdf). This policy is equivalent to the EPA Guidance for planning.

For each project, project objectives need to be clearly identified and designated as primary or secondary. Primary objectives are those that are critical to meeting the goals of the research activity. Secondary objectives are ancillary to the primary objectives and often provide additional information that supports the primary objective. Associated measurements must then be classified as either critical for primary objectives or non-critical for secondary objectives. This allows a better focus for the planned QA activities (e.g., audits).

In instances where routine steps are used for sampling, analysis, data searching, or other activities the preparation and use of an SOP is of significant value. In these instances an SOP should be written, especially if the procedure is to be followed by more than one person. SOPs are descriptions of repetitive functions written to a level of detail that allows the function to be performed in the same way between personnel and over time. They may describe, for example, fundamental programmatic actions and technical actions such as analytical processes, and processes for maintaining, calibrating, and using equipment. SOPs are intended to be specific to the organization or facility whose activities are described and assist that organization to maintain their quality control and QA processes and ensure compliance with governmental regulations. If a new procedure needs to be developed under this HF Research Program, L/C/O QMPs should be consulted. The need for an SOP is determined by the Key Investigator, QAM, or line management. SOPs will be reviewed and approved per L/C/O QMPs.

8. Implementation of Work Processes -

Proper implementation of a project requires:

1. - Adherence to all planning and procedural documents (QAPPs, written operating procedures), with documentation of any significant deviations or amendments.

2. - Routine QC checks and periodic self-assessments to provide regular, ongoing quantitative and qualitative evaluation of project performance. Where measurement quality objectives have been established, the Key Investigator is responsible for ensuring that all resulting project design constraints are adhered to and that all associated data quality requirements for specific measurement methods are routinely met.

3. - Timely reporting and documentation of significant problems, corrective actions taken, and potential impact on task/project results.

4. - Complete, accurate, verifiable documentation of all aspects of the task/project conduct that may affect the quality of the results and the overall credibility and defensibility of the work. This includes documentation of experimental objectives, approach, sample chain-of-custody (COC), methods, and materials.

5. - QA review of all products produced in this HF Research Program.

All members of ORD's research staff are required to comply with ORD Policies 13.2 (9), *Paper Laboratory Records*, and 13.4 *Quality Assurance/Quality Control Practices for ORD Laboratories Conducting Research* (9). It is the responsibility of the Key Investigator or COR for each project of the HF Research Program to ensure that a project is implemented properly so that the results are scientifically defensible and of the type and quality required.

The Key Investigator or COR is directly responsible for ensuring that all personnel involved in the conduct of the project are appropriately qualified, trained, and supervised. He/she is also responsible for ensuring that all project personnel fully understand the research objectives, the technical and QA or QC requirements of all of the project's research plans and procedures, and their roles and responsibilities in implementing these plans and procedures and in the overall conduct of the project.

QAPPs and associated SOPs are to be available on the site of testing and the work shall be implemented according to those planning documents. SOPs that are written for projects should follow L/C/O guidance.

QAPP/SOP revisions are required whenever significant changes to a plan or procedure are implemented. QAPPs and project-related SOPs must be reviewed on a yearly basis for long-term projects. Reviews should be documented, using a memo, and tracked with all QAPPs and SOPs.

National Institute of Standards and Technology -traceable standards will be used, as available, for calibration of equipment and/or to confirm the quality of generated data. Second source standards

must be included in the calibration for analytical systems. Where no such standards exist, other means will be used to establish the quality of the data, including agreement with established scientific knowledge and historical data, reproducibility and internal consistency, comparability between different measurement techniques, and conformity with approved technical plans and directives.

9. Assessment and Response -

Regular technical assessment of project operation, systems, and data (including existing/secondary data) will be conducted under this HF Research Program. In most cases the assessments are described in the project planning documents (QAPP) and scheduled by the Key Investigator in coordination with the associated L/C/O QA staff who will perform the assessment.

As defined in the EPA QA/G-7, *Guidance on Technical Audits and Related Assessments for Environmental Data Operations*, (27) a technical assessment is "a systematic, objective, and independent examination of a project during its implementation phase to determine whether environmental data collection activities and related results comply with the project's QAPP and other planning documents, are implemented effectively, and are suitable to achieve its data quality goals." Types of assessments which will be performed to support the HF Research Program are described below with frequency and responsibilities identified in Table 2.

- **Quality System Audits (QSAs)** are management independent qualitative evaluations of a quality management system. They review the management structure, policies, and procedures of an operation. For this HF Research Program, a QSA will be conducted to ensure the HF Research Program is being conducted according to this QMP. A QSA will be performed by the ORD Director of QA within one year of this QMP approval. The QSA report will be sent to the Study Coordinator, the Overall Technical Research Lead, their supervisors, the NPD, and the PQAM. The supervisors of the leads will have the ultimate responsibility for ensuring corrective actions have been completed for any QSA findings.
- **Technical systems audits (TSAs)** qualitatively document the degree to which the procedures and processes specified in the approved QAPP are being implemented. TSAs will be performed by L/C/O QAMs for all HF Research Program projects early in the project or when the QAM and Key Investigator determines it is most appropriate; TSA requirements will be included in each QAPP and will focus on critical target analytes. TSA reports are to include who and what was assessed; any problems (e.g. Findings) and noteworthy practices identified; and recommended corrective actions. TSA reports are submitted, at a minimum, to the Key Investigator, the appropriate supervisor, the COR for extramural audits, and the PQAM. The issues and corrective actions that are to be enacted due to the audits are to be tracked by the L/C/Os QA staff. The Key Investigators are responsible for ensuring corrective action is implemented. The PQAM will track corrective actions for Findings across the HF Research Program using a spreadsheet. L/C/O QAMs will provide quarterly status updates to the PQAM.
- **Performance evaluations (PEs)** quantitatively test the ability of a analytical system to obtain acceptable results. PEs need to be conducted on all critical measurements (where available). If a contract or Regional laboratory is not currently participating in a PE program, it will be provided with PEs by the Key Investigator in consultation with the QAM.
- **Verification of Data** is the process of evaluating the completeness, correctness, and conformance/compliance of a specific data set against the method, procedural, or contractual requirements (28). Data collected during this HF Research Program are to undergo verification

against the generic requirements such as the analytical method or contract. Verification is performed by the data generators (laboratories) and Key Investigator or Technical Research Lead, as identified in the associated QAPP.

- **Audits of data quality (ADQs)** are conducted by QA staff on verified data to document the capability of a project's data management system (hardcopy and/or electronic) to collect, analyze, interpret, and report data as specified in the QAPP. ADQs assess the effectiveness of the "big picture," as opposed to data verification, which concern individual data points. ADQs will be conducted on a representative sample of critical data generated early in the project. For example, a representative sample may be the first complete data package for the critical target analytes from the first sampling event. The NRMRL SOP *Performing Audits of Data Quality (ADQs)* (29) (http://intranet.epa.gov/nrmintra/lsas/eqmp/pdf/SOPLSASQA020.pdf) can be consulted for example guidance regarding ADQs.
- **Data usability assessment** entails using the information collected during data verification and ADQs to assess whether the data can be used for the intended purposes. In some cases data may have been collected where not all quality objectives were met, or sampling and handling may have impacted the analytes. Under these conditions the data may be rejected or used with certain conditions or qualifications attached to the results. These assessments are performed by the Key Investigator or Technical Research Lead, as identified in the associated QAPP.

Other assessments which may be useful (optional):

Readiness reviews are conducted before specific technical activities (e.g. laboratory analysis) are initiated to assess whether procedures, personnel, equipment, and facilities are ready for environmental data to be collected according to the QAPP. QA staff in consultation with investigators will determine the need for readiness reviews for any aspect of the HF Research Program.

Surveillance is used to continuously or periodically assess the implementation of an activity or activities to determine conformance to established procedures and protocols. QA staff in consultation with investigators will determine the need for surveillances for any aspect of a specific project.

Table 2. Assessment Frequency and Responsibilities

Assessment Type	Frequency	Responsibility to Plan	Responsibility to Implement	Reports are Provided to[1]
QSA	Within 1 year of QMP approval	ORD Director of QA	ORD Director of QA	PQAM, Study Coordinator, Overall Technical Research Lead, NPD
TSA	At least once for each project	Key Investigator, COR, L/C/O QAMs	L/C/O QAMs	PQAM, Key Investigators, CORs, Technical Research Leads associated with the project
PE	For each critical measurement, if an applicable PE is available	Key Investigator and QAM	Key Investigator and QAM	Key Investigator, QAM, PQAM
Data Verification	Each data set associated with a project	Key Investigator	Data generator and Key Investigator and supporting personnel	In project report
ADQ	Representative sample of each critical measurement associated with a project	Key Investigator, L/C/O QAMs	L/C/O QAMs	PQAM, Key Investigators, Technical Research Leads associated with the project
Data Usability Assessment	Each data set associated with a project	Key Investigator	Key Investigator and supporting personnel	In project report
Readiness Reviews	Prior to start of new procedures as needed	Key Investigator	Key Investigator and supporting personnel	NA
Surveillances	Throughout HF Research Program as needed	Key Investigator, L/C/O QAMs	L/C/O QAMs	NA

[1]The supervisors of those listed are also copied.

When significant quality issues are encountered, the Key Investigator should be contacted as soon as possible. Assessors do not have stop work authority; however, they can advise the Key Investigator if a stop work order is advisable, such as situations where data quality may be significantly impacted. The Key Investigator makes the final determination as to whether or not to issue a stop work order.

10. Quality Improvement

Quality improvement begins with every staff person involved with this HF Research Program. The policies and procedures described in this QMP document the QA planning and implementation steps for this HF Research Program with the procedures in place for assessment described in Section 9. It is the responsibility of each L/C/O staff, and especially QAMs and the PQAM, to monitor these quality procedures throughout the data life cycle.

The primary means for discovering opportunities for continuous quality improvement will be the systematic technical assessments in use within the entire HF Research Program's Quality Management System. These assessments, as discussed in Sections 2 and 9, will provide information from which the HF Research Program can learn and improve upon. Staff is encouraged to immediately report to their Key Investigator any QA concerns and to communicate regularly with their colleagues on project progress and potential issues or steps for improvement.

11. Terms and Definitions -

Assessment. The evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: quality systems audit, technical systems audit, and audit of data quality.

Audit of data quality. An examination of a set of data after it has been collected and verified by project personnel, consisting of tracing representative test data from original recording through transferring, calculating, summarizing and reporting. It is documented in a data audit report.

Data quality objectives. The qualitative and quantitative statements derived from the DQO process that clarify a study's technical and quality objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions.

Director of Quality Assurance (DQA). A Director of Quality Assurance (DQA) has lead responsibility for the mandatory Agency-wide QA program for each of the ORD Laboratories and Centers.

DQO process. A systematic planning process that clarifies research objectives and establishes a basis for the types, quality, and quantity of data required. It provides a method for establishing DQOs for a research project.

Lead Organization. The organizational home of the Key Investigator with project lead responsibilities is by definition the Lead Organization (i.e., Laboratory, Center, Division, or Immediate Office).

Technical System Audits. Technical systems audits are thorough, systematic, on-site, qualitative audits of facilities, equipment, personnel, training, procedures, recordkeeping, data validation, data management, and reporting aspects of a system.

Performance Evaluations. Performance evaluations are a type of audit in which the quantitative data generated in an analytical system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

Program Quality Assurance Manager (PQAM). The QAM who serves in the lead QA role for a research effort. Their role is typically described in a QMP. This individual is typically a QAM for a Division in ORD or is a Director of QA for an ORD Laboratory or Center.

Quality Assurance Project Plan (QAPP). A document describing in comprehensive detail the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

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